TECHNICAL SECTION COMPLETE LETTERS

I. PURPOSE

This document establishes standardized language to assure the uniformity of the Office of New Animal Drug Evaluation's (our) technical section complete (TSC) letters. We only issue TSC letters when the sponsor seeks phased review under an Investigational New Animal Drug (INAD) file.

II. CONTENT OF TECHNICAL SECTION COMPLETE LETTERS

In the following paragraphs describing the content of our TSC letters, any wording identified by italics provides instruction to the preparer about what information you should add. Wording in the examples that is not italicized is boilerplate language and you should not modify it.

A. First paragraph

Based on the information in your submission dated <*insert date*> and the information contained in <*list all relevant files,*> the Division of <*name*> considers the <*technical section name*> technical section for <*identify drug*><*insert proposed intended uses*> to be complete. <*For target animal safety TSC letters also include the following two sentences in the first paragraph:*> This technical section complete letter represents our finding that the laboratory studies essential to determining target animal safety are complete and accepted. We also evaluate target animal safety in our review of other technical sections, particularly the effectiveness and all other information technical sections.

B. Middle paragraphs

<In these paragraphs, you will explain how we came to the decision that the technical section is complete and provide any other related information that you need to convey to the sponsor. Paragraphs that need to be included in specific TSC letters follow.>

1. For Chemistry, Manufacturing, and Controls TSC letters

   <Include all of the following paragraphs.>

   Under current good manufacturing practice (cGMP) regulations (21 CFR 211 and 226), you are required to validate your manufacturing processes. This validation provides assurance that the manufacturing processes will reliably meet predetermined specifications. This validation is demonstrated by documenting that the manufacturing processes are adequate to preserve the identity, strength, quality, and purity of the new animal drug. If your validation information was not available or was found deficient at the time of the pre-approval inspection, you should contact FDA after you complete manufacturing validation and before you ship the product. A product that does not conform to cGMP is adulterated under section 501(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC 351(a)(1)(B)).

   An expiration date of <*XX*> months is acceptable for this product.

2. For Environmental Impact TSC letters based on our concurrence with a sponsor's claim for categorical exclusion

   <Include all of the following paragraphs.>

   In your submission, you claimed a categorical exclusion under 21 CFR 25.<*insert the appropriate citation*> for the approval of <*drug*> <*for intended uses and conditions of use if not previously stated*>. Furthermore, you stated that to your knowledge, no extraordinary circumstances exist that may significantly affect the human environment. We agree that the approval of <*drug*> for <*intended uses and conditions of use*> falls within the categorical exclusion under 21 CFR <*insert the appropriate citation*> and we are not

aware of any extraordinary circumstances. Therefore, neither an environmental assessment nor an environmental impact statement is required.

If there are changes in the product (e.g., indication, dosage, duration of use) before you submit your New Animal Drug Application (NADA), please contact the primary reviewer immediately to determine if the categorical exclusion remains appropriate for the action. Please include a copy of this letter in your NADA submission at Section 10 (Form FDA 356V), Environmental Assessment. When you submit your NADA, your signature on the 356V re-certifies that the conditions of the categorical exclusion are still applicable at the time of your NADA submission.

C. Last substantive paragraph

We will make a final decision on whether we can approve your application after we have reviewed all of the data for all applicable technical sections submitted in support of an Administrative NADA <*insert* New Animal Drug Application (NADA) *in lieu of NADA if the acronym has not previously been spelled out in the letter*>, NADA, or supplemental NADA, and any other information available to us, as a whole, and determined whether the requirements for approval set forth in the Federal Food, Drug, and Cosmetic Act have been met.

D. Closing paragraph

If you submit correspondence relating to your submission to the investigational file, you should reference the date and the principal submission(s) identifier found at the top of this letter. If you have any questions, please contact me at <*phone number*> or <*name of alternative contact*>, at <*alternative contact's phone number*>.

III. FORMATTING AND SIGNATURE BLOCK

Please refer to P&P 1243.3010 for our information on proper letter format and style conventions, including signature block. Technical section complete letters should be prepared for the division director's (or staff leader's) signature.

III. REFERENCES

Program Policy and Procedures Manual

1243.3010, Format and Style Conventions for Letters

IV. VERSION HISTORY

November 16, 2001

ONADE Reviewers Manual revised and incorporated into CVM's Program Policy and Procedures Manual; this is the original P&P version.

August 19, 2003

Revised to reference P&P 1243.7220 (Environmental review: Evaluating claims of categorical exclusion for actions relating to new animal drugs) for those TSC letter paragraphs.

January 26, 2006

Revised to include target animal safety TSC language approved by ONADE Management on January 24, 2006, to ensure consistency between existing procedures, and to incorporate the language for the environmental impact TSC letter from P&P 1243.7220 (where it will be deleted).